UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL NO. 1456** C.A. No. 01-12257-PBS
THIS DOCUMENT RELATES TO: ALL ACTIONS	Judge Patti B. Saris

CERTAIN NAMED PLAINTIFFS' OBJECTIONS TO CLASS COUNSEL'S PROPOSAL TO REDISTRIBUTE THE TRACK TWO CONSUMER ALLOCATION

I. INTRODUCTION.

Certain Named Plaintiffs hereby object to "Class Counsel's Proposal to Redistribute the Track Two Consumer Allocation" (hereinafter "Proposal") for the reasons that follow, which supplement the reasons previously given in their objection papers and at the Fairness Hearings.

By their proposal to "redistribute" the consumer settlement proceeds, Class Counsel concede a number of important points relevant to this Court's ruling on the "fairness, reasonableness and adequacy" of the proposed Track 2 settlement pursuant to Rule 23(e).

First, by "suggest(ing) that the manner in which the monies allocated to the Class 1 and Class 3 consumers in the proposed settlement ***should be modified***" because the "distribution formula preliminarily approved by the Court … ***did not reasonably reflect*** each consumer's damages for the Class drugs", they concede that they have materially undermined this Court's preliminary approval decision. Proposal at 1. If the prior distribution formula was "not reasonable", by Class Counsel's own admission, this Court could not find the same to be "reasonable" pursuant to Rule 23(e). Further, the Class notice approved by this Court – which was based upon the Court's erroneous preliminary approval decision concerning an admittedly

unreasonable consumer distribution formula – failed to properly and fairly apprise the Class about the terms of the settlement, the consumer allocation and the promised distribution. All of these terms were material to the settlement agreement signed by the parties in 2007, and all were material to the Notice that had to be provided to the Class.[1] As a result, and at a minimum**, the entire Class 1 and 3 consumers need to be re-noticed to apprise them of these material alterations to the settlement**.[2]

Second, by suggesting that their proposed "redistribution" formula based upon purported "damage" estimates is somehow "***more accurate***" and "***more cogent***" [Proposal at 1] – *i.e.*, more relevant and valid – than the prior formula based upon consumer out-of-pocket payments" (as calculated by CMS data, for Class 1, and consumer "estimation", for Class 3), Class Counsel concede **the prior formula was less valid and reliable**.[3] However, despite its apparent unreliability now, Class Counsel inexplicably continue to insist that Class 3 consumers follow the prior invalid distribution formula in order to recover a Class 3 settlement payment.[4] Further, in choosing to abandon the "consumer out-of-pocket payment" distribution formula in favor of a "damage"-based formula, Class Counsel fail to apply that formula evenhandedly to all brand-

[1] As discussed more fully below, the Notice also was not sent to the nearly 17 million consumer Medicare beneficiaries who received brand name Class B drugs erroneously labeled "generic" and "multi-source" drugs. These consumers should get the best practicable notice.

[2] The expense of such re-notice should be borne by the settling parties – not the Class – who decided to change gears at the June 13, 2011 Fairness Hearing.

[3] In other words, it was a colossal waste of time and money for Class Counsel to pursue CMS data showing consumer drug payments, only to throw out the distribution matrix that relied upon such data to pay claims. Again, the cost of such wasteful spending should be borne by the settling parties, not the Class. The settlement fund should be reimbursed these expenditures.

[4] *See* Proposal at 2, n. 3 ("Under the Full Estimation Refund Option, a Class 3 consumer must have provided an estimate of their total out-of-pocket expenditures during the Class Period for each Class drug for which they seek reimbursement and at least one form of documentary proof that they incurred a percentage co-pay or cash obligation outside of Medicare Part B.")

name, injectable drugs at issue. There are dozens of such drugs inexplicably dumped into the category of "Class B drugs".[5] Damages can and should have been calculated for such drugs. However, Class Counsel chose to not examine the "damages" for these drugs because it would have further skewed the already deficient consumer payouts under their proposed "redistribution".

Finally, Class Counsel apply neither distribution formula to the settlement payments for Epogen. Instead, they simply distribute the available leftover funds to all Epogen purchasers (in both Classes 1 and 3, without differentiating between the two Classes) on a flat payment basis. This is perhaps the most serious affront to consumers within the proposed "redistribution" as Class Counsel have simply commandeered the entire $5,477,030.75 Epogen settlement fund and "redistributed" it to other Class members – in the hallow name of "damage" redistribution. If, in fact, Epogen purchasers suffered no damages, as Class Counsel now contend (but contrary to their position in their Complaint and throughout this litigation), then no settlement payment should be made. Class Counsel's new offer of a flat payment of $53.28, which bears no rhyme or reason to either "out-of pocket payments" or "damages", provides no reasonable basis for approving a settlement of Epogen claims.[6]

---

[5] For instance, as discussed more fully below, the following exemplar brand-name injectable drugs treat cancers and other serious diseases (for which this Court has routinely called for an award of double and treble damages for the "Heartland period") and should have been included in Class A for which "double damages" are presently being proposed: Calicijex (Abbott), Camptosar (Pfizer), Eligard (Aventis), Gamimune N (Bayer), Gammagard (Bayer), Leukine (Aventis), Neosar (Pfizer), Novantrone (Immunex), Prograf (Fujisawa), Taxotere (Aventis), Trelstar (Pharmacia), and Zemplar (Abbott). The total branded PADs in Class B have a combined "Consumer Recognized Loss" that exceed the total of the proper Class B generic drugs. *See* Dkt. No. 7648 (Ex. "D" to the Decl. of Daniel Coggeshall).

[6] In view of Class Counsel's newfound disbelief that Epogen purchasers suffered any "damage", those consumers should be notified that they are free to pursue their claims against Amgen in whatever court they believe they can establish damages, since the Court-appointed Class Counsel

Third, and most important, the present "redistribution" formula only masks the flaws in the underlying settlement allocation between TPPs and consumers which was the product of a conflicted allocation negotiation.[7] Class Counsel suggest that their proposed "redistribution" is needed "to align the Track Two settlement with the approaches used in the AstraZeneca and BMS settlements." Proposal at 1. However, in BMS, as the Court well knows, when a substantial shortfall in consumer payouts was identified by the objection of Reverend Aaronson, the allocation between TPPs and consumers (which was the product of the same PAL-tainted negotiation) was "re-allocated", and consumers received more than $1 million more in settlement proceeds. Here, Class Counsel have been emboldened by their ability to raid the settlement claims database to try to find suitable substitute class representatives (as well as this Court's issuance of a seeming blank check right of replacement). Consequently, though they espouse "hope" that "[m]ediation efforts led by Professor Green … will continue", they provide no reason for such false hope, given their rigid stance on the insufficient 17.5% consumer allocation. Proposal at 2 n.2. Plainly, there is not enough money to pay consumers a fair settlement. There is not enough money because, at the time they negotiated the settlement and allocation, Class Counsel (1) erroneously underreported "Class A" drugs (shifting dozens of brand name injectable drugs to Class B), (2) erroneously included Epogen as a drug for which "damages" could be recovered (given their present position), (3) erroneously established the

---

have conceded they are inadequate to zealously advance such consumers' interests in this litigation.

[7] As detailed in prior filings of record, consumer Class interests were inadequately represented by conflicted counsel from PAL and HCFA. Such conflict was not "cured" by this Court referring the matter of HFCA's withdrawal to Magistrate Judge Bowler. Instead, because Judge Bowler refused to decide the ultimate question of the adequacy of the consumer representation in this case, that matter rests squarely with this Court, which has already acknowledged the propriety of its recusal to avoid any appearance of partiality.

"split" of the settlement proceeds between Class A and B drugs (based upon (1) and (2) above), (4) appointed inadequate representatives of consumer interests in the TPP/consumer allocation negotiation, only to (5) have themselves join the fray in the end in an effort to "redistribute" the allocated portion to try to prevent an obvious injustice, such as "Easy Pay" consumers receiving $2.04, rather than the promised $35.

All these eleventh-hour machinations by Class Counsel simply demonstrate their inadequacy to have served consumer Class interests in conjunction with the Track 2 litigation and settlement. Although this Court has demonstrated it will never second-guess itself on such issue, at some point the weight Class Counsel ask this Court to bear in protecting them (and, by extension, their substantial fee interests) – in the face of obvious conflicts of interest, unexplained delays, and demonstrably inadequate representation of consumer interests – should break the resolve of any impartial court to approve a settlement at all costs.

II. THE PROPOSED "REDISTRIBUTION" CONTINUES TO UNDERCOMPENSATE CONSUMERS

In a separate pleading, Certain-Named Plaintiffs have opposed the Track 2 Defendants' support of their expansion of the list of Subject Drugs in this case to include 85 Newly-Added Drugs. *See* Dkt. No. 7652. That pleading sets forth in detail how Class Counsel and Track 2 Defendants doubled the group of Class B drugs from 92 to 177, in violation of two prior Court Orders barring the expansion of the drugs in this case.

Beyond the fact (made clear in the aforesaid pleading) that this inclusion of 85 Newly-Added Drugs has substantially diluted the pro rata distribution of Class B settlement proceeds – such that such consumers are paid a mere 5.83% of their Total Recognized Losses for such drugs – there remains the further problem created by the failure of Class Counsel in their proposed redistribution to account for the fact that many of the drugs in Class B are actually brand name,

physician-administered drugs ("PADs"), for which the consumer claims are strongest and about which this Court has routinely required double or triple damages. Class Counsel completely avoid this significant issue by improperly labeling all the drugs in their Class B drug list as "generic" or "multi-source" drugs for which, they claim, "there is very little spread marketing evidence…". Proposal at 6. Indeed, it is because these drugs are allegedly generic, with interchangeable J-codes and reimbursement schemes based on median AWP, that Class Counsel claim "the Class B damages are *de minimis (sic)"* and only deserving of "modest payout[s]". *Id.* Class Counsel are wrong in their assessment of the universe of Class B drugs. This Court need only look to the words of both Class Counsel (in their complaint) and Track 2 Defendants (in their opposition to Track 2 Class Certification).

In their operative complaint, the Revised Fifth Amended Master Consolidated Class Action Complaint (RFAMCC) (Dkt. No. 5902), Class Counsel list dozens of brand name PADs. *See* Chart at Exhibit "A" hereto. The attached chart simply extracts examples from the RFAMCC wherein Class Counsel listed the brand name PADs that they now seek to include in the last of Class B generics. They should not be permitted to do so. It is one thing to settle a claim for a certain drug based upon an assessment of liability and the prospects of recovery; it is quite another to wrongly ascribe to such drug a character one knows it does not have, simply to garner settlement approval.

The complaint further details the spreads for certain of these brand named PADs. *See* Chart of examples of spreads at Exhibit "B" hereto (taken from the RFAMCC). These spreads were extracted from documents produced by the Department of Justice and other government investigations, as well as Track 2 Defendants' own documents produced in the litigation. Again,

Class Counsel provide no explanation for now labeling these drugs as multi-source, generics for which spread damages cannot be calculated.

The Track 2 Defendants have weighed in on this issue as well in their opposition to Class Counsel's motion for Track 2 class certification. In particular, Track 2 Defendants filed a Motion to Strike the "Generics Chart" filed by Class Counsel. *See* Dkt. Nos. 3499, 3500. In that pleading, Defendants challenged Class Counsel's drug chart as "inaccurate and unsubstantiated." Dkt. No. 3499 at 1. Defendants submitted their own chart, attached as Exhibit "B" to the pleading (Dkt. No. 3500), in which they set forth (from their own personal knowledge of their drugs), which drugs were single source, brand name PADs versus multi-source generics. *See* Dkt. No. 3500. Among the drugs Defendants agreed were single source PADs, and thus should have been included as Class A drugs in the Track 2 settlement, are the following examples: Taxotere (Aventis), Aggrastat (Baxter), Brevibloc (Baxter), Cisplatin (Baxter), Claforan (Baxter), Osmitral (Baxter), Recombinate (Baxter), Koate (Bayer), Kogenate (Bayer), Mithracin (Bayer), Nebupent (Fujisawa), Prograf (Fujisawa), Leukine (Immunex), and Novantrone (Immunex). Just because Track 2 Defendants now wish to settle drug claims against them, they cannot be permitted to reverse course and avoid the consequences of having argued that each of these drugs is a single source, brand name, injectable medication, properly included within the Class A group of drugs and properly compensated at double or treble damages (even under the proposed redistribution).

One reason Class Counsel has given as to why Class B drugs are compensated at the self-described "modest payout" of 5.8281% (Proposal at 6) is because they claim to have "legitimate concerns that such damages (for multi-source Track 2 drugs) could be *de minimus*." Dkt. No. 7573 at 12. They base this claim on their dual contentions that (1) there are problems identifying

the manufacturer of multi-source, generic drugs, and (2) the spread evidence is supposedly lacking. However, because dozens of Class B drugs are in fact single source brands, they don't meet Class Counsel's criteria for *de minimus* damage treatment and "modest payouts" from the settlement fund. In the Complaint, Class Counsel listed actual evidence showing spreads far in excess of the Hartman "30% speed limit" even assuming the same is properly applied to consumers, which Certain-Named Plaintiffs do not concede. *See* Exhibit "B" hereto. For instance, the Complaint makes the following specific allegations about spreads for Class B drugs:

Toposar: "Table 2 is an analysis of a certain dosage of Abbott's drug Toposar from a document entitled "2000 Manufacturer Listing of Pharmaceutical Awards – IVMed." (ABT AWP/MDL 031000-23) (Highly Confidential)." [8]

Table 2

Drug	**Contract Price**	**AWP**	**$ Diff AWP**	**% Spread**
Toposar (etoposide inj)	26.32	286.63	260.31	989.01

Epogen: "Spreads for the 10,000 u/ml ten pack for Epogen were historically approximately 33%, but beginning in January 2000 Amgen implemented a series of AWP increases so that by 2002 the spread increased to 42%." (RFAMCC ¶233B).

Gammagard: "According to Baxter's own documents, the published AWPs for Gammagard S/D were higher than the actual prices provided to wholesalers. In a customer announcement dated September 24, 1996, Baxter increased the AWP for one particular dosage of Gammagard S/D from $640.71 to $737.00, and the WAC from $365.00 to $420.00. The difference between

[8] RFAMCC ¶228.

the new AWP and the new WAC ($317.00) constituted a 43% spread. (BAX MDL 005366) (Highly Confidential)." (RFAMCC ¶295).

Gamimune: "In a DHHS OIG report (*see* OEI-03-00-00310 (P006398-006424)), the government also discovered that the AWP for all immune globulin pharmaceuticals (of a dosage of 5g), including Bayer's Gamimune® (Bayer was one of five manufacturers of the dosage listed in the 1997 *Red Book*), were over inflated by an average spread of 32.21%." (RFAMCC ¶307).

Pharmacia: "Table 1 is an analysis of certain dosages of P&U drugs from a document entitled "Oncology Express CONTRACT PRICING" (PH011977) (Highly Confidential)."[9]

Table 1

PRODUCT	LIST	AWP	CONTRACT PRICE	DIFFERENCE (between AWP and contract price)	PERCENTAGE SPREAD
Adriamycin	883.80	1104.13	119.00	985.13	828%
Adrucil	12.83	16.04	4.56	11.48	252%
Amphocin	29.01	36.26	13.00	23.26	179%
Neosar	80.22	100.28	16.15	84.13	521%
Toposar	614.81	768.51	33.84	734.67	2,171%

The above examples demonstrate that Class Counsel were fully aware that the spreads for these Class B drugs exceeded even the Hartman 30% speed limit long after they settled the Track 2 case. *See* Dkt. No. 5902 (RFAMCC, filed February 17, 2009). It is noteworthy that the settling parties – both Class Counsel and Track 2 Settling Defendants – stipulated to the filing of the RFAMCC because it was "in furtherance of the proposed Track 2 settlement". *See* Dkt. No. 5919 (Stipulation filed February 18, 2009). Consequently, the averments of the RFAMCC can and should be considered as binding against the settling parties for purposes of this Court's

[9] RFAMCC ¶453.

assessment of the proposed Track 2 settlement and the redistribution of the consumer settlement proceeds.

Beyond the "spread marketing" evidence contained in the RFAMCC, publicly available documents demonstrate that substantial spread marketing evidence exists as to the brand named PADs now included in the Class B drug list. In fact, such evidence demonstrates that many of these Class B drugs belong in Class A (along with the Class A drugs included in the BMS settlement).

For instance, Exhibit "B" to the Track 2 settlement (Dkt. No. 5133-2) lists the drug "doxorubicin" as a Class B drug. However, as the settling parties well know doxorubicin is a cancer chemotherapy sold under two brand names: Adriamycin, manufactured by Track 2 defendant Pharmacia or Rubex, manufactured by BMS. *See* Wikipedia at Exhibit "D" hereto. The Court is well aware of the fact that Rubex was and remains a Class A drug under the BMS settlement. However, Pharmacia's brand Adriamycin appears nowhere in Exhibit "B", even though Class Counsel are fully aware that Pharmacia's doxorubicin (Adriamycin) competed directly with BMS's Rubex. *See, e.g*. Exhibit "C" hereto (a September 29, 1995 memo produced by Pharmacia to Congress talking about Pharmacia offering competitive spreads for doxorubicin to compete with BMS's Rubex brand). As Class Counsel's own Complaint attested, "[f]or a drug like Adriamycin, the reduced pricing offered AOR (an oncology practice organization) a reimbursement of over $8,000,000 profit when reimbursed at AWP. *See* RFAMCC at ¶444. As the chart at Exhibit "B" hereto demonstrates, the spreads on Pharmacia's doxorubicin, as reported by the Department of Justice in 2001, were 632%.

The source document obviously utilized by DOJ, and then by Class Counsel in their RFAMCC, demonstrates the spreads for other Class B listed drugs were well in excess of the

Hartman 30% speed limit. *See* "AOR/Pharmacia and Upjohn Proposal" at Exhibit "E" hereto (attachment 1, listing spreads for Adriamycin, Adrucil, Bleomycin, Neosar, Toposar, Vincasar, Amphocin, Cytosar-U, Depo Provera, Camptosar). But while Class Counsel saw fit to rely upon this document in framing their RFAMCC, they completely ignore the reference in the first page to the fact that Pharmacia's version of Lupron/Zolodex, Triptorelin (Trelstar), was being established with a "pricing mechanism…with spreads favoring AOR versus" Lupron and Zolodex. This "partnership proposal" to AOR clearly indicated that "this pricing advantage would increase profitability to AOR". With comparable spreads to Lupron and Zolodex, Class Counsel and Pharmacia, as the proponents of the settlement of Trelstar claims, must do more to demonstrate fairness, reasonableness and adequacy of their proposed settlement of Trelstar, especially the basis for treating it as a Class B drug with a 5.8% recovery. The settling parties fail to make any proffer as to why the Class of Trelstar and Eligard purchasers should accept anything less than the dollars and percentage recoveries provided to Lupron and Zolodex purchasers in their respective settlements. In MDL1430, as this Court likely knows, Lupron consumers received $150 million, and 50% of their out of pocket payments, in settlement. In the AstraZeneca/Zolodex settlements in this Court, consumers have received double damages and a total settlement that far exceeds the Track 2 settlement. Trelstar and Eligard purchasers here get a petty 5.8%, a demonstrably insufficient and unreasonable settlement amount.

There is a good reason for why Class Counsel have chosen to substantially underpay the claims of the brand name Class B drugs: they don't have enough money in the allocated consumer share (17.5%) of the overall $125 million settlement. But that is reason enough to reject the allocation – as in BMS – and force a more equitable allocation from the TPPs. Since Class Counsel invite a comparison to the BMS settlement, as cause for approving their proposed

"redistribution", the Track Two settlement redistribution falls woefully short of what was achieved in BMS.

At the outset, the original allocation of the $19 million settlement fund was 23% for consumers and %77 for TPPs. This resulted in proportionate shares, net of attorney's fees, of $$3,146,400 and $10,241,000 respectively.

After Reverend Aaronson objected – as he does again here – the Court ordered the parties to mediate a re-allocation, which they did. This time, however, the conflicted PAL and HFCA consumer representatives were excluded from the process. The undersigned counsel for Rev. Aaronson participated. The result was an increase in the consumer share of $1,000,000, representing a "reallocation" to 28.26% for consumers versus %71.74 for TPPs. The increase of 5.26% helped to make up the shortfall in the consumer settlement payouts, which was the principle objection of Rev. Aaronson. Rev. Aaronson also negotiated payment of an incentive fee for his participation, and signed a private settlement agreement whereby he agreed to withdraw his objection.

Here, Class Counsel have had no interest in settling. Instead, they have simply bullied their way through to final approval, imposing their will upon the Certain Named Plaintiffs and the consumer Class. Since they have chosen to have the fairness, reasonableness and adequacy of their settlement adjudged by this Court, both independently and in comparison with both AstraZeneca and BMS, the Court should proceed to do so.

We have already shown how the comparable branded PADs to AstraZeneca's Zoladez (which settled for more than the entire Track 2 settlement combined) – Aventis's Eligard and Pharmacia's Trelstar – have been lumped improperly into Class B. At 5.8281% (per the Coggeshall Declr., Dkt. No. 7648 at 4), the $2,920,988.32 in "Total Recognized Losses" (*id*. at

9,10) will receive a paltry $170,238.12. And, that is for the Class members who were lucky enough to receive notice of the settlement. (Mr. Thomson – a Trelstar purchaser – received no such notice). Had Class Counsel done what they were supposed to do, and sent first class mail notice to all Class A drug purchasers, the claims rate surely would have been higher (based upon the prior experience in this case each time new, better notice is disseminated).

Also in BMS, the Class received new notice to alert them about the material change in the terms of the settlement. While Class Counsel gloss over the 4 consumer objections received, these objections provide an important window into the mistakes that happened in BMS, and how they can and should be avoided in Track 2. Indeed, if the Court were to approve the present Track 2 settlement, it would have to do so over the objections of all of the former Track 2 class representatives. The Class should be apprised of this important fact. The Class should also be apprised of the fact that this consumer settlement is ratably less than settlements achieved for Lupron, Zoladex, and BMS. In other words, it is the lowest consumer AWP settlement by far – both in terms of aggregate dollars paid and individual claim amounts.

Lastly, Class Counsel simply assume – in their proposed redistribution -- that this Court will award them attorney's fees of 30%.[10] This Court should follow its Lead in BMS and tax Class Counsel for their delays and wasteful spending. The Class should not be charged for incompetent legal services.

[10] The topic is conspicuously absent from Class counsel's Proposal, but the "assumption" of a 30% fee award appears in the Coggeshall Declaration, Exhibit "B" (deducting attorney's fees of $37,500,000.00

Dated: July 6, 2011

Respectfully submitted,

/s/ Donald E. Haviland, Jr.
Donald E. Haviland, Jr., Esquire
Robert G. Hughes, Esquire
Michael J. Lorusso, Esquire
HAVILAND HUGHES, L.L.C.
111 S. Independence Mall East
The Bourse, Suite 1000
Philadelphia, PA 19106
Telephone: (215) 609-4661
Facsimile: (215) 392-4400

CERTIFICATE OF SERVICE

I, Donald E. Haviland, Jr., hereby certify that on July 6, 2011 the foregoing Certain Named Plaintiffs' Objections to Class Counsel's Proposal to Redistribute the Track Two Consumer Allocation was filed via CM/ECF and all counsel of record were served via ECF notification.

/s/ Donald E. Haviland, Jr.
Donald E. Haviland, Jr.